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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,228	04/24/2001	Stanley Stewart Davis	8567-604US(WESR/P21724US)	6578

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PHILADELPHIA, PA 19103-7013

EXAMINER

HOWARD, SHARON LEE

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 08/11/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/841,228	DAVIS ET AL.	
	Examiner Sharon L. Howard	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 3/4/03, 3/17/03, 3/25/03, 4/28/03.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-7, 9-11 and 15-17 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-7, 9-11 and 15-17 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \*    c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14-16.

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

Applicant's arguments filed on 4/28/03 have been fully considered and they are persuasive.

The examiner acknowledges receipt of IDS filed on 3/4/03 and 3/17/03, Supplemental IDS filed on 3/25/03 and one month extension of time.

Claims 1,2 and 9 have been amended.

Claim 8 has been cancelled.

New claims 15-17 have been added

Claims 1-7,9-11 and 15-17 are now pending in this application.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3,7,11 are rejected under 35 U.S.C. 102(b) as being anticipated by Ducharme et al. (U.S. Patent No. 5,840,746).

Ducharme teaches a pharmaceutical composition and a method for treating pain, comprising an oil-in-water emulsion (col.11, lines 1-10), and NSAIDs (i.e. non-steroidal anti-inflammatory drugs) which are dispersed in the emulsion. Ducharme teaches the drugs consist of COX-1 and COX-2 inhibitors (col.2, lines 35-49). Ducharme teaches that the oily phase may be a vegetable oil such as arachis oil (col.10, lines 51 and 52, col.11 lines 3 and 4) which is a hydroxylated oil.

The prior art meets the limitations of the instant application.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3,7,11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ducharme ('746).

Ducharme is discussed above.

Ducharme does not particularly teach the amount of the drug.

However, Ducharme teaches the amount of the drug will vary depending upon the host treated and the particular mode of administration (see col.11, lines 50-67).

Claims 1-7,9-11,15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ducharme et al. ('691) in combination with Collins et al. (U.S. Patent No. 6,096,728).

Ducharme is applied above.

Ducharme does not teach a particular non-steroidal anti-inflammatory drug.

However, Collins teaches a pharmaceutical composition comprising the particular drug consisting of flurbiprofen and ibuprofen (col.29, lines 12 and 13). Collins teaches a method for treating pain and Parkinson's disease (col.2, lines 10-67, col.2, lines 1 and 2) with said composition. Collins also teaches that the composition comprises COX2

inhibitors (col.32, lines 22-34). Collins generically teaches emulsions (col.26, lines 33-35).

Both references teach pharmaceutical compositions comprising non-steroidal anti-inflammatory drugs and method for treating pain. It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. (See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)).

The expected result would be a pharmaceutical composition comprising an oil-in-water emulsion and a non-steroidal anti-inflammatory drug which is dispersed in the emulsion.

One having ordinary skill in the art would have been motivated to prepare a third composition by including a particular non-steroidal anti-inflammatory drug into the composition of Ducharme, because a third composition can be used for the same purpose for treating pain and one would expect to achieve similar beneficial results.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (703) 308-4359. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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746-3121 for regular communications and (703) 305-3592 for After Final  
communications.

Any inquiry of a general nature or relating to the status of this application or  
proceeding should be directed to the receptionist whose telephone number is (703) 308-  
1234.

*Sharon Howard*

Sharon Howard  
August 8, 2003

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SUPERVISORY PATENT EXAMINER  
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